RECEIVED
CENTRAL FAX CENTER
AUG 14 2006

REMARKS

This Amendment responds to the July 14, 2006 Office Communication (the "Communication"). The Communication was issued in response to the applicants' March 3, 2006 Amendment, which was deemed by the examiner to be non-responsive due to amendments to the claims which introduced subject matter from non-elected claims.

1. Objections to the Claims

The examiner objected to the preambles of claims 36 and 62. The applicants have revised these claims to recite "A method of releasing cholecystokinin peptide in a subject..." Based on this amendment, the applicants have overcome the informality objection. The examiner is requested to withdraw the stated rejection accordingly.

2. Amendments to the Claims

The applicants have made several amendments to independent claims 36 and 62 to bring these claims into conformity with conventional claims drafting practices. For example, the claims have been amended to recite that the compound being administered is a polypeptide-oligomer conjugate, which was clearly indicated by subparagraphs i), ii), and iii) as originally presented.

Claims 36 and 62 have also been revised to recite that the "luminal cholecystokinin releasing factor polypeptide-oligomer conjugate or luminal cholecystokinin releasing factor polypeptide" integrates into the cell membrane of the gut epithelium and further that the "luminal cholecystokinin releasing factor polypeptide-oligomer conjugate or luminal cholecystokinin releasing factor polypeptide" binds with a target receptor on the surface of an epithelial cell. This amendment is supported, inter alia, by the limitations 41, 42, 44, 45 and 46 which recite various embodiments in which the oligomers are coupled to the LCRF polypeptide using hydrolyzable and/or non-hydrolyzable linkages. Other support is found, for example, at page 14 of the application as filed, in the first paragraph which states: "In covalently bonded peptide applications, the polymers may be functionalized and then coupled to free amino acid(s) of the peptide(s) to form labile bonds which permit retention of activity with the labile bonds intact. Removal of the bond by chemical hydrolysis and proteolysis then enhances the peptidal activity." Page 18, first paragraph, states "As a result of these improved characteristics the invention

PAGE 11/15 * RCVD AT 8/14/2006 2:13:06 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/13 * DNIS:2738300 * CSID:9192868199 * DURATION (mm-ss):05-06

contemplates parenteral and oral delivery of both the active polymer-peptide species and, following hydrolytic cleavage, bioavailability of the peptide per se, in vivo applications." The last sentence of page 19 discusses use of "a hydrolyzable linker at K19 to protect the peptide from trypsin proteolysis." The third paragraph of page 16 discusses use of a non-hydrolyzable linker at the N-terminus. The last sentence of page 36 discusses use of a hydrolyzable bond which permits the oligomer to be hydrolyzed off to permit the LCRF to bind its receptor. The first paragraph of page 37 discusses the "addition of a hydrolyzable oligomer at the C-terminus [to] provide resistance to degradation by carboxypeptidases," and further discusses the "removal of all the oligomers by hydrolysis [to] regenerate the active LCRF for full biological activity." Many other examples are found throughout the specification.

Claims 36 and 62 are also amended to make other minor grammatical revisions to prepare the claims for allowance.

No new matter has been added by any of the above amendments, and thus, the Examiner is respectfully requested to enter the amendments.

3. **Novelty of the Claimed Invention**

The USPTO has failed to present a *prima facie* case that the Spannagel et al. reference renders claims 36 and 62 unpatentable under 35 USC § 102(b).

As repeatedly stated by the Court of Appeals for the Federal Circuit, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.[1] Thus, it is well settled that *each and every element* must be must be described. Moreover, it is well settled that each element must be described *as set forth in the claim.*

As previously presented, claim 36 recited that the luminal cholecystokinin releasing factor (LCRF) polypeptide comprised "an oligomeric moiety attached to the N-terminus" and "an

[1] See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 223 USPQ 1264, 1270 (Fed. Cir. 1984); *Connell v. Sears, Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984).

PAGE 12/15 * RCVD AT 8/14/2006 2:13:06 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/13 * DNIS:2738300 * CSID:9192868199 * DURATION (mm-ss):05-06

oligomeric moiety attached to the lysine residue." Thus, the claim recites not the administration to a subject of a naked LCRF polypeptide, but administration to the subject of an LCRF polypeptide-oligomer conjugate having "an oligomeric moiety attached to the N-terminus" and "an oligomeric moiety attached to the lysine residue."

The administration of an LCRF polypeptide-oligomer conjugate is not taught described by Spannagel et al., thus it cannot be maintained that Spannagel et al. teaches *each and every element* of claim 36, nor can it be maintained that Spannagel et al. teaches each element *as set forth in claim* 36. Nor has the examiner even asserted that these elements are present in Spannagel et al.; consequently, the examiner has not presented a *prima facie* case of unpatentability under § 102.

The examiner argues that "limitations such as comprising a lysine residue are viewed as inherent properties because they are not actual method steps." This argument appears to conflate two different issues, i.e., the issue of whether a product limitation can render a method claim novel, and the doctrine of inherency.

With respect to the first question, whether a product limitation can render a method claim novel, it is well-established that all claim limitations must be considered when evaluating patentability. For example, MPEP § 2116.01 states that "[a]ll the limitations of a claim must be considered when weighing the differences between the claimed invention and the prior art in determining the obviousness of a process or method claim." In the same section, the MPEP states (emphasis added):

> ***Interpreting the claimed invention as a whole requires consideration of all claim limitations. Thus, proper claim construction requires treating language in a process claim which recites the making or using of a nonobvious product as a material limitation.... The decision in Ochiai specifically dispelled any distinction between processes of making a product and methods of using a product with regard to the effect of any product limitations in either type of claim.***

See also MPEP § 2143.03 (emphasis added):

PAGE 13/15 * RCVD AT 8/14/2006 2:13:06 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/13 * DNIS:2738300 * CSID:9192868199 * DURATION (mm-ss):05-06

> ***"All words in a claim must be considered in judging the patentability of that claim against the prior art."*** In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The rule is no different when considering patentability under § 102. A claim is anticipated under 35 U.S.C. § 102 only "if each and every limitation is found either expressly or inherently in a single prior art reference."[2] Consequently, the examiner cannot avoid considering the product limitations in claims 36 and 62. Spannagel does not teach each and every one of the limitations set forth in these claims. Consequently, Spannagel et al. cannot form an adequate basis for a rejection under § 102.

Further, the doctrine of inherency relied upon by the examiner does not fill the gaps in the USPTO's burden of proof. The doctrine of inherency relates to the discovery of a previously unappreciated property. As quoted in MPEP "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer."[3] The applicants are not aware of any doctrine that would, as suggested by the applicant, render a product limitation inherent and therefore lacking in novelty simply because it is present in a method claim but is not a method step. Any such rule would be in serious conflict with the rules clearly stated above, which require all elements of a method claim to be considered regardless of whether they are method steps or elements of a product.

The examiner simply has not made a case that each and every limitation of the applicants' claims 36 and 62 are present in Spannagel et al. Instead, the examiner has attempted to make a case that the specifically recited limitations can simply be ignored. As discussed above, the limitations of the claims cannot be ignored. Indeed, the USPTO bears the burden of establishing that the limitations are present in a single reference in order to establish a case of unpatentability under § 102. The examiner has not made this case. Accordingly the applicants respectfully request that the examiner withdraw the stated § 102 rejections.

---

[2] *Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1343 (Fed. Cir. 2001).
[3] *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999) (as quoted in MPEP § 2112).

PAGE 14/15 * RCVD AT 8/14/2006 2:13:06 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/13 * DNIS:2738300 * CSID:9192868199 * DURATION (mm-ss):05-06

Atty. Docket No. 014811-96.22DV
Application. No. 10/633,966
Amendment Responsive to June14, 2006 Office Communication

CONCLUSION

Based on the foregoing discussion, applicant respectfully submits that the pending claims are now in condition for allowance. The Examiner is respectfully requested to withdraw the informality objection to the specification and the claims and to withdraw the 35 USC § 102(b) rejection of claims 36 and 62, in view of Spannagel, et al.

If any issues remain outstanding incident to the allowance of the application, the Examiner is requested to contact the undersigned attorney.

FEES PAYABLE

The applicants hereby petition for a one month extension of time, extending the deadline for responding to the June 14, 2006 Office Action from July 14, 2006 to August 14, 2006 and resulting in an extension fee of $120. The Commissioner is hereby authorized to charge this fee and any additional fee found necessary for entry of this supplemental amendment to **Deposit Account No. 13-4365** of Moore & Van Allen PLLC.

Respectfully submitted

8/14/06
Date

Marianne Fuierer
Attorney for Applicants
Registration No.: 39,983
Moore & Van Allen PLLC
Phone: (919) 286-8089

PAGE 15/15 * RCVD AT 8/14/2006 2:13:06 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/13 * DNIS:2738300 * CSID:9192868199 * DURATION (mm-ss):05-08